K092669

510(K) SUMMARY: AGFA DX-D IMAGING PACKAGE

Common/Classification Name: Computed Radiography System, 21 CFR 892.1650
Proprietary Name: DX-D Imaging Package
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jeffery A. Jedlicka, Prepared: August 18 2009
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NOV - 6 2009

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DX-D Imaging Package. The predicate devices are two devices with similar technology: Agfa's Computed Radiography Systems with NX Workstations (K090672) and Varian Medical's PaxScan 4030 (K024147).

B. DEVICE DESCRIPTION

The new device is a direct radiography imaging system of similar design and construction to the predicates. Agfa's DX-D Imaging Package uses Agfa's familiar NX workstation with MUSICA^{2}™ image processing and flat panel detectors of the scintillator-photodetector type. Flat panel detectors with scintillators of both Cesium Iodide (CsI) and Gadolinium Oxysulfide (GOS) are available. The device is used to capture and digitize x-ray images without a separate digitizer common to computed radiography systems.

Principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

Agfa's DX-D Imaging Package has the same intended use as the predicate devices; namely to provide diagnostic images to assist the physician with diagnosis.

The device uses Agfa's flat panel detectors with amorphous silicon scintillators and NX workstations with MUSICA^{2} image processing to create radiographic images of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D Imaging Package has a similar Indications For Use statement as the legally marketed predicate device (Agfa DX-S with NX workstation). The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D Imaging Package is substantially equivalent to a prior Agfa computed radiography systems (K090672) and to a similar Varian direct radiography system (K024147). The new device has an indications statement largely similar to that of the Agfa predicate. Intended uses of all the devices are the same, namely to provide diagnostic quality images.

F. TESTING

The new device combines proven technology from both predicates. It combines the NX user workstation of the Agfa predicate with flat panel detectors of the Varian predicate. Differences between the new device and the predicates are minor and have been evaluated via laboratory testing and in an image comparison study.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AGFA Healthcare Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 23 2013

Re: K092669
Trade/Device Name: DX-D Imaging Package
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: October 5, 2009
Received: October 29, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of November 6, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092669

Device Name: **DX-D Imaging Package**

Indications for Use:

Agfa's DX-D Imaging Package is indicated for use in providing diagnostic quality images to aid the physician with diagnosis.

Systems can be used with MUSICA^2 image processing to create radiographic images of the skeleton (including skull, spinal column and extremities) chest, abdomen and other body parts.

Agfa's DX-D Imaging Package is not indicated for use in mammography.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092669